DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

JUL 27 2015

MISDER Medical, LLC
% Evergreen Research, Inc.
Ms. Nancy Sauer
433 Park Point Drive, Suite 140
Golden, Colorado 80401

Re: K120821
Trade/Device Name: LLICS Laparoscopic Lens Internal Cleaning System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCT, GCJ
Dated (Date on orig SE ltr): March 16, 2012
Received (Date on orig SE ltr): March 19, 2012

Dear Ms. Sauer,

This letter corrects our substantially equivalent letter of May 11, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120821

Device Name: Laparoscopic Lens Internal Cleaning System (LLICS™)

Indications for Use:

The LLICS™ is indicated for use in laparoscopic surgeries to clean the laparoscope lens within the surgical cavity, preventing temperature changes associated with lens fogging.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R.P. Ogden for mpa

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K120821

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5. 510(k) Summary

MAY 11 2012

Sponsor Information

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Contact Person: Ken Maydew

This 510(k) summary was prepared on April 18, 2012.

Device Identification

Proprietary Name: LLICS™ Laparoscopic Lens Internal Cleaning System

Common or Usual Name: Endoscope Lens Cleaning Device

Classification Name: Endoscope and/or Accessories

Classification: Class II, Gastroenterology/Urology, GCJ, KOG

Intended Use

The LLICS™ is used to clean the lens of a laparoscope or other endoscope without removing the device from the surgical cavity. Cleaning the laparoscope inside the surgical cavity helps to prevent fogging of the lens due to temperature changes.

Comparison to Legally Marketed Devices

The LLICS™ system is substantially equivalent to the D.H.E.L.P. heated endoscope lens protector manufactured by New Wave Surgical. This product was cleared by 510(k) K062779. It is also substantially equivalent to Clear Field Sterile Wipes, manufactured by Tucson Medical Corporation. This product was cleared under 510(k) K974454.

The LLICS system has the same general intended use as these legally marketed devices. They are all intended to preserve or restore visibility through the endoscope by removing soil and preventing fogging of the lens. The 510(k)-cleared indication statements differ in that the predicate devices do not specifically list lens cleaning, only defogging. This difference in terminology does not create a new intended use and does not raise new safety concerns.

The LLICS system relies on the same basic principle as these legally marketed products. The endoscope lens is cleaned using a piece of foam or soft cloth moistened with a cleaning/defogging solution.

The LLICS system and the D.H.E.L.P. system both use strategies to maintain endoscope temperature as a means to prevent fogging of the endoscope lens. LLICS maintains endoscope

temperature by allowing the surgeon to clean the lens within the surgical cavity. D.H.E.L.P. maintains endoscope temperature by providing a battery-powered heated chamber in which to clean the lens.

The LLICS system differs from these two legally marketed devices in that it is introduced into the surgical cavity through a trocar/cannula. However, many other endoscope accessories are introduced into the surgical cavity via a surgical trocar/cannula. One example is the PMC Laparoscopic Instruments, manufactured by PMC Medical, GmbH. These laparoscopic accessories were cleared through 510(k) K101193.

Device Description

The LLICS sterile system is intended for single-procedure use. Each LLICS package includes two cleaning swabs that can be introduced through an existing surgical trocar or cannula and one bottle of surfactant.

Each cleaning swab consists of a foam tip mounted on a plastic rod, an outer cannula, and an actuator handle.

The surfactant is applied to the foam tip on the cleaning swab. The tip is then retracted into the LLICS cannula before it is introduced through the surgical trocar/cannula. The LLICS cannula helps to keep the foam tip clean while it passes through the existing surgical trocar/cannula.

Once the LLICS device has passed through the surgical trocar/cannula, the surgeon visualizes the end of the LLICS cannula and uses the actuator handle to deploy the surfactant-moistened foam tip. The actuator handle remains outside the body and can be operated with one hand. The surgeon uses the foam tip to clean the endoscope lens and then retracts the tip into the LLICS cannula. The retracted device can be left in the surgical trocar/cannula for additional cleaning cycles or removed to make the trocar/cannula available for introducing other endoscope accessories.

Summary of Non-Clinical Test Results

Biocompatibility Testing

- The product was sterilized with E-Beam radiation at higher than the maximum dose prior to testing. Surfactant was applied to the foam tip, as for normal use. The patient-contacting portions of the device were tested for cytotoxicity, sensitization, and irritation. The device passed all tests.
- This suite of biocompatibility testing is typical of the testing required for invasive surgical instruments.
- The test results support safe use of the LLICS system within the surgical cavity.

Cleaning Performance

- Fully assembled, sterilized product was used to clean an endoscope that had been soiled with bacon fat and/or tissue. To better simulate actual use, the LLICS swab was passed through a surgical trocar, and the tester manipulated the swab using only the portions of the device that would remain outside the body during use. A standardized visual

reference was used to demonstrate both thorough soiling of the lens and ability of the LLICS system to restore good visibility. The system was able to restore the specified level of visibility over multiple cleaning cycles.

- These test results demonstrate that the materials and design of the LLICS system are appropriate and effective for the intended use.

Durability Testing

- Fully assembled, sterilized product was put through multiple rounds of simulated cleaning cycles to simulate wear on the components and materials. The test cycle includes deployment of the tip, wiping the lens, and retracting the foam tip. The insertion portion of the device remained intact during the testing and no foam was shed after an average of 29 cycles.
- These test results support safe use of the LLICS system within the surgical cavity.

Usability Testing

- Simulated use testing was conducted, involving surgical nurses, scrub technicians, and laparoscopic surgeons. The testing was carried out in a surgical suite. The lens cleaning operation was carried out inside a laparoscopic training unit. The participants had access to the instructions for use but had no other training or assistance prior to or during the test.
- The testing confirmed that the nurses and scrub technicians could remove the device from its sterile packaging and prepare it for use without use errors that could cause the product to be contaminated.
- The testing also confirmed that surgeons could complete the cleaning process under simulated use conditions, without damaging the LLICS swab or the endoscope.
- These test results demonstrate that the product design, packaging, and labeling meet the needs of the intended user population.
- Nurses are able to detect when a foam tip is not intact.

Conclusions

The LLICS system is substantially equivalent to other legally marketed endoscope accessories, including laparoscope lens defogging devices and a variety of manual laparoscope accessories that are introduced into the surgical cavity during laparoscopic procedures.